

Application Number 10/698,291  
Response to Office Action mailed December 28, 2007

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**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

Claim 1 (Previously Presented): A neurostimulation lead comprising:

- a lead body having a proximal end and a distal end;
- a plurality of stimulation electrodes disposed adjacent the distal end of the lead body; and
- a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

Claim 2 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes an elastic material.

Claim 3 (Original): The neurostimulation lead of claim 1, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 4 (Previously Presented): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a shape memory alloy.

Claim 5 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a super-elastic material.

Claim 6 (Canceled).

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Claim 7 (Original): The neurostimulation lead of claim 1, further comprising an inner lumen to accommodate a stylet.

Claim 8 (Original): The neurostimulation lead of claim 1, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 9 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 10 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 11 (Original): The neurostimulation lead of claim 1, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 12 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 13 (Original): The neurostimulation lead of claim 1, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 14 (Original): The neurostimulation lead of claim 1, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 15 (Previously Presented): The neurostimulation lead of claim 1, wherein the plurality of electrodes include at least four electrodes.

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Claim 16 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 17 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 18 (Currently Amended): The neurostimulation lead of claim 1, wherein the ~~of the~~ fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 19 (Currently Amended): The neurostimulation lead of claim 1, wherein the ~~of the~~ fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 20 (Original): The neurostimulation lead of claim 1, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 21 (Original): The neurostimulation lead of claim 1, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 22 (Previously Presented): A neurostimulation system comprising:

- an implantable neurostimulation pulse generator;
- a lead body having a proximal end and a distal end;
- a plurality of stimulation electrodes disposed adjacent the distal end of the lead body;
- an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes; and
- a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

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Claim 23 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes an elastic material.

Claim 24 (Original): The neurostimulation system of claim 22, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 25 (Previously Presented): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a shape memory alloy.

Claim 26 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a super-elastic material.

Claim 27 (Canceled).

Claim 28 (Original): The neurostimulation system of claim 22, further comprising an inner lumen to accommodate a stylet.

Claim 29 (Original): The neurostimulation system of claim 22, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 30 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 31 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

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Claim 32 (Original): The neurostimulation system of claim 22, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 33 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 34 (Original): The neurostimulation system of claim 22, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 35 (Original): The neurostimulation system of claim 22, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 36 (Original): The neurostimulation system of claim 22, wherein the electrodes include at least four electrodes.

Claim 37 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 38 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 39 (Currently Amended): The neurostimulation lead of claim 22, wherein the ~~of the~~ fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 40 (Currently Amended): The neurostimulation lead of claim 22, wherein the ~~of the~~ fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

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Claim 41 (Original): The neurostimulation system of claim 22, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 42 (Previously Presented): A method comprising:

inserting a lead introducer into a patient;

inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, a plurality of stimulation electrodes disposed on the lead body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes and the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site; and

removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand.

Claim 43 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand.

Claim 44 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least a portion of the lead introducer, thereby releasing the fixation mechanism to expand.

Claim 45 (Original): The method of claim 42, further comprising:

detaching a distal end of each wire-like element; and

withdrawing the lead from the target site.

Claim 46 (Original): The method of claim 42, further comprising:

restraining the expanded fixation mechanism; and

withdrawing the lead from the target site.

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Claim 47 (Original): The method of claim 42, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 48 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 49 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 50 (Currently Amended): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 6 to 15 mm.

Claim 51 (Currently Amended): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 9 to 12 mm.

Claim 52 (Original): The method of claim 42, wherein each of the wire-like elements includes an elastic material.

Claim 53 (Currently Amended): A stimulation lead comprising:  
a lead body having a proximal end and a distal end;  
a plurality of stimulation electrodes disposed on the lead body; and  
means for fixing the lead body relative to tissue proximate a tissue target ~~stimulation~~ site, wherein the fixing means includes wire-like elements that are expandable to fix the lead body at ~~the~~ the tissue target site, wherein the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes.

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Claim 54 (Original): The lead of claim 53, wherein each of the wire-like elements includes an elastic material.

Claim 55 (Original): The lead of claim 53, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 56 (Previously Presented): The lead of claim 53, wherein each of the wire-like elements includes a shape memory alloy.

Claim 57 (Original): The lead of claim 53, wherein each of the wire-like elements includes a super-elastic material.

Claim 58 (Original): The lead of claim 53, further comprising means for restraining the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraining means.

Claim 59 (Original): The lead of claim 53, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 60 (Previously Presented): The neurostimulation lead of claim 1, further comprising a plurality of retainer rings, wherein the retainer rings mount the wire-like elements to the lead body at proximal ends and distal ends of the wire-like elements

Claim 61 (Previously Presented): The neurostimulation lead of claim 1, wherein the fixation mechanism is spring-biased.

Claim 62 (Previously Presented): The neurostimulation system of claim 32, wherein the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion.



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Claim 63 (Previously Presented): The neurostimulation system of claim 62, wherein the elastic portion of the lead body decreases in length upon removal of the stylet.

Claim 64 (New): The neurostimulation lead of claim 1, wherein at least one of the electrodes comprises a ring electrode.

Claim 65 (New): The neurostimulation system of claim 22, wherein at least one of the electrodes comprises a ring electrode.

Claim 66 (New): The lead of claim 53, wherein at least one of the electrodes comprises a ring electrode.

Claim 67 (New): The method of claim 42, wherein inserting the lead into the patient via the introducer comprises advancing the lead through the introducer to the target tissue site within an epidural space or proximate to a sacral foramen.